DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 1-16-2008. Claims 17 & 21 have been amended. Claims 1-13, 18-20, 31-37, and 40-44 have been cancelled.

Applicant's comments directed to the 103(a) rejection of claims 14-16 and 38 are noted, however, are not persuasive. Particularly, applicant stated that the Office Action was not clear with regards to the coagulation body is supported on the elongated body distal region. The Swanson et al reference discloses that the spline element (172) can be attached to the elongated body (184) distally (column 17 lines 22-23), thus, making the spline (172) the distal region of the elongated body (184), thereby, it is clearly that the coagulation body is supported on spline element (172), which is indeed the distal region of the elongated body (184). With regards to applicant's comments directed to the previous Office Action ignoring the "inflatable" aspect of the coagulation body, The Swanson et al discloses the size & spacing of the electrodes (28) on various structures can vary. Alternatively, the electrodes (28) can be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. As mentioned in the previous Office Action, embodiment of Figures 82-84 illustrates the inflatable aspect of the coagulation/electrode body. Clearly, it would have been obvious to one skilled the art to use the probe of Figure 25 utilizing the alternative inflatable electrode of Figures 82-84 in a procedure that would require additive heating effects during tissue contact. Applicant's comments directed to claim 16, the Swanson et al reference discloses the electrode (28) can serve

many different purposes, being a sensing element is one of them (column 7 lines 45-48). For purposes of demonstrating for claim 16, Figure 25 illustrates 5 different electrodes (28), it is not out of the ordinary to assign one of the five electrodes (28) to be a sensing element while assign the rest of the other four electrodes (28) to the alternative electrodes of Figures 82-84 for ablating/coagulating purposes. With regards to the limitations recited in the wherein statement in claim 16, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. The 103(a) rejection applied to claims 14-16 and 38 in the previous Office Action stand rejected.

Claims 17 & 21, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 & 17 recites the limitation "the distal end" in line 7 and in line 6, respectively. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Crowley (U.S. Patent No. 5,715,825). Swanson et al reference discloses the embodiment of Figure 25 comprising an elongated body (184) comprising a catheter carried within the outer member (12), the distal region of the elongated body (184) includes a flexible spline (172) that includes a hinge portion (186). This embodiment further comprising a coagulation portion (182) but with regards to the coagulation body being inflatable, Swanson et al discloses alternatively, the electrodes (28) can be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. The Examiner maintains that it would have been obvious to provide the inflatable structure from the embodiment of Figures 82-84 on the embodiment of Figure 25 to provide an alternative treatment device, such as during a procedure that would require additive heating effects during tissue contact.

Regarding claims 15, 16, the embodiment of figure 25 includes the coagulation body proximal to the hinge element and the electrodes (28) can be used to sense in heart tissue (column 7 lines 45-48). With regards to the limitations recited in the wherein statement in claim 16, particularly required the "sensing element" electrode on one side of the hinge portion and the

"coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 17 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Crowley (U.S. Patent No. 5,715,825). Swanson et al discloses in Figure 82 a probe comprising an elongated body (424) comprising a catheter carried within the outer member or sheath (442) interior bore, the distal end (426) of elongated body (424) operably connected to the distal end (440) of outer member or sheath (442). Figure 84 illustrates the tissue coagulation structure (430) supported on elongated body (424) distal region. With regard to claim 17 reciting the half-balloon structure, Swanson et al discloses in Figure 84 each whole expandable structure (430) comprises the "half-balloon" structure, thus, deemed to have "half-balloon" structure. With regards to claim 17 now further defining the shape of the half-balloon structure that is asymmetric about the longitudinal axis of the elongate body distal region in a plane perpendicular to the longitudinal axis of the longitudinal body distal region, such asymmetric half-balloon shape is within ordinary skilled in the art particularly to procedures that requires asymmetric heating/ablating, resulting in asymmetric balloon as taught by Crowley (column 3 lines 46-53). Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's balloon structure (430) of Figure 84 such that it would be half-balloon asymmetric about the longitudinal axis in the plane

perpendicularly to the longitudinal axis, as pointed out by Crowley suitable for applications asymmetric heating/abating.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012), modified above by Crowley (U.S. Patent No. 5,715,815) and further in view of Thompson et al (U.S. Patent No. 6,152,920). Swanson et al, presented above, discloses a tissue coagulation probe comprising elements as recited in these claims but does not suggest the hinge has a greater flexibility in the bending direction than the flexibility in the elongated body that are immediately proximal & distal thereto. Thompson et al discloses in Figures 14 & 15 a surgical probe (108) comprising a sheath (114) carried within an outer shaft (116), the sheath (114) defining a distal loop (110) supporting a plurality of electrodes (54) and a distal end connected to the outer shaft (116), the sheath (114) including a hinge portion (126) located proximal of the distal end, the hinge portion (126) is provided with a greater flexibility in the bending direction than the flexibility in the sheath (114) that are immediately proximal & distal thereto. Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's probe to include a hinge, taught by Thompson et al for purposes of providing greater flexibility in the distal region of elongated body (184).

Claims 21-30, and 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Thompson et al (U.S. Patent No. 6,152,920). Swanson et al, presented above, discloses a tissue coagulation probe comprising elements as recited in these claims, particularly to independent claims 21 and claim 25, the

Swanson et al discloses the embodiment of Figure 25 comprising an elongated body (184) comprising a catheter carried within and extended outwardly from the outer member's (12) interior bore such that the distal region forms a loop including a cap or a hinge portion (186) defining the apex of the loop structure (170), the cap or hinge portion (186) is formed in the spline (172).

Regarding claim 22 reciting the control element, the embodiment of Figure 25 illustrates control elements (180, 192) associated with the distal end of elongated body (184) extending along the exterior of the elongated body (184).

Regarding claim 23, the embodiment of Figure 25 illustrates the loop structure (170) length is at least 2 times the loop height.

Regarding claim 26, the embodiment of figure 25 includes the coagulation body proximal to the hinge element and the electrodes (28) can be used to sense in heart tissue (column 7 lines 45-48). With regards to the limitations recited in the wherein statement in claim 26, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With regards to claim 27, the Swanson et al discloses alternatively, the electrodes (28) can be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. The Examiner maintains that it would have been obvious to provide the

inflatable structure from the embodiment of Figures 82-84 on the embodiment of Figure 25 to provide an alternative treatment device, such as during a procedure that would require additive heating effects during tissue contact.

Regarding claims 28 & 29, the embodiment of Figures 82-84 illustrates each whole expandable structure (430) comprises the "half-balloon" structure, thus, deemed to have "half-balloon" structure, and the structure (430) comprises porous material (column 35 lines 49-51).

Regarding claim 30 reciting the "heated structure", the Swanson et al embodiment of Figures 82-84 discloses fluid (438) can be introduced to expand the structure (424) interacting with electrodes (429) to generate heat, which is consistent applicant's specification on page 13 lines 1-22, thus, meets the cited "heated structure" limitation.

Regarding claims 21 & 45, however, the Swanson et al reference does not suggest the hinge has a greater flexibility in the bending direction than the flexibility in the elongated body that are immediately proximal & distal thereto. Thompson et al discloses in Figures 14 & 15 a surgical probe (108) comprising a sheath (114) carried within an outer shaft (116), the sheath (114) defining a distal loop (110) supporting a plurality of electrodes (54) and a distal end connected to the outer shaft (116), the sheath (114) including a hinge portion (126) located proximal of the distal end, the hinge portion (126) is provided with a greater flexibility in the bending direction than the flexibility in the sheath (114) that are immediately proximal & distal thereto. Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's probe to include a hinge, taught by Thompson et al for purposes of providing greater flexibility in the distal region of elongated body (184).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
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